K113251

DEC 2 1 2011

2.2 510(k) Summary – MatrixMANDIBLE Preformed Reconstruction Plates

Name of Firm:	Synthes 1301 Goshen Parkway West Chester, PA 19380
510(k) Contact:	Elizabeth Kierzek Associate Regulatory Affairs Specialist Phone: 610-719-6565 Fax: 484-356-9682 Email: Kierzek.Elizabeth@synthes.com
Date Prepared:	November 1, 2011
Device Trade Name:	Synthes MatrixMANDIBLE Preformed Reconstruction Plates
Device Generic Name:	Plate, bone
Product Code:	JEY
Regulation Number:	872.4760
Predicate Devices:	Synthes MatrixMANDIBLE Preformed Reconstruction Plates (K091144)
Device Description:	The Synthes MatrixMANDIBLE Preformed Reconstruction Plates are anatomically contoured to match the body and angle regions of the mandible in most patients. These plates are designed for use with Synthes MatrixMANDIBLE screws that come in multiple diameters and lengths to meet the anatomical needs of the patient. System components are manufactured in either titanium or titanium alloy and are intended for single use only.
Intended Use / Indications for Use:	The Synthes MatrixMANDIBLE Preformed Reconstruction Plates are intended for use in oral and maxillofacial surgery, trauma and reconstructive surgery. This includes primary mandibular reconstruction, comminuted fractures and temporary bridging pending delayed secondary reconstruction, including fractures of edentulous and/or atrophic mandibles, as well as unstable fractures.

Comparison of the technological characteristics of the device to the predicate device:	The design features, material, and indications for use of the subject MatrixMANDIBLE Preformed Reconstruction Plates are substantially equivalent to the predicate device identified. Additionally, the safety and effectiveness of this system is adequately supported by documentation within this submission.
Performance Data (Nonclinical and/or Clinical):	Synthes conducted the following non-clinical testing: dynamic and static testing. The conclusions drawn from testing demonstrate that the MatrixMANDIBLE Preformed Reconstruction Plates maintain a significantly longer fatigue life compared to the 2.5mm thick MatrixMANDIBLE plates when tested under similar loading conditions. Clinical data was not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Alan Haley
Regulatory Affairs Specialist
Synthes Incorporated
1302 Goshen Parkway
West Chester, Pennsylvania 19380

DEC 2 1 2011

Re: K113251
Trade/Device Name: Synthes MatrixMANDIBLE Preformed Reconstruction Plates
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: December 12, 2011
Received: December 14, 2011

Dear Mr. Haley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES CMF

9 Indications for Use Statement

510(k) Number: K113251 (if known)

Device Name: Synthes MatrixMANDIBLE Preformed Reconstruction Plates

Indications for Use:

The Synthes MatrixMANDIBLE Preformed Reconstruction Plates are intended for use in oral and maxillofacial surgery, trauma and reconstructive surgery. This includes primary mandibular reconstruction, comminuted fractures and temporary bridging pending delayed secondary reconstruction, including fractures of edentulous and/or atrophic mandibles, as well as unstable fractures.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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